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MAR -5 1996

Mr. Richard J. Litner  
Nutrinfo  
40 Spring Street  
P.O. Box 1097  
Watertown, Massachusetts 02272-1097

Dear Mr. Litner:

This is in response to your letter to the Food and Drug Administration (FDA) dated January 4, 1996, on behalf of your client, J.B. Harris, Inc., Glenview Illinois, requesting that FDA clarify the agency's position concerning the claims made for the product Sambucol.

In a letter to FDA of September 28, 1996, J.B. Harris, Inc. stated that they were making the following statement in the labeling of the product Sambucol:

Sambucol is a safe and effective virus control  
Sambucol stops viruses in the throat before they spread.

As we stated in our letter to Mr. Schnall, dated December 29, 1995, these statements evidence that this product is intended for other than food use within the meaning of section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act), in that it is intended for use as an antiviral agent. The common sense usage of the term anti-viral is in the prevention or treatment of virus-mediated diseases or conditions. Therefore, these claims do not qualify as a section 403(r)(6) claim. Use of these claims on the label or in the labeling of this product may subject it to regulation under the drug provisions of the act.

If your client intends to make claims of this nature, he should contact FDA's Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

Robert J. Moore, Ph.D.  
Senior Regulatory Scientist  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals

97S-0163

LET 2

# J. B. HARRIS INC.

4324 Regency Drive  
Glenview, IL 60025

September 28, 1995

Victor Fratelli, PhD.  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street  
HFS-455  
Washington, DC 20204

Dear Dr. Fratelli,

Notice is hereby given pursuant to the requirements to Section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and in the labeling in connection with the marketing of the dietary supplement Sambucol™. Sambucol™ was first marketed with these statements of nutritional support on September 16, 1995. The statements of nutritional support are as follows:

- Sambucol™ is a safe and effective virus control.
- Sambucol™ stops viruses in the throat before they spread.

Very truly yours,

J. B. HARRIS, INC.

  
Harris Schnall  
President

HS:ng

cc: Richard J. Littner  
Nutrinfo Corporation

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